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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,703	09/26/2001	Subba Reddy Palli	A01020B	8135

7590

11/24/2004

RheoGene Holding Inc  
2650 Eisenhower Avenue  
Norristown, PA 19403

EXAMINER

MURPHY, JOSEPH F

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/965,703

Applicant(s)

PALLI ET AL.

Examiner

Joseph F Murphy

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 8-10, 13, 14 and 16-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 6, 7, 12 and 15 is/are rejected.
- 7) ☒ Claim(s) 1, 3-5 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### ***Formal Matters***

Claims 1-36 are pending. Claims 8-10, 13-14, 16-36 stand withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 1-7, 11-12, 15 are under consideration.

### ***Response to Amendment***

The objection to the Specification has been obviated by Applicant's amendment and is thus withdrawn.

The objection to claim 1 is withdrawn.

The rejection of claims 1-3 under 35 U.S.C. 102(a) as being anticipated by Martinez et al. (1999) has been withdrawn.

The rejection of claims 1-6, 11-12 under 35 U.S.C. 103(a) as being unpatentable over Martinez et al. (1999) in view of U.S. 59191667 (Gage et al.) has been withdrawn.

New issues are set forth below.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Leonhardt et al. (1998).

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The instant claims are drawn to a gene expression modulation system wherein the first gene expression vector comprises a DBD and an LBD; and a second gene expression vector which comprises a transactivation domain and an LBD not from USP. The Leonhardt reference teaches utilizes the mammalian two-hybrid system to examine the role of ligand in the dimerization of human progesterone receptor (hPR). The GAL4 DNA-binding domain and the herpes simplex virus VP16 transactivation domain were fused to the amino terminus of full-length hPR (both the A and B isoforms) to produce chimeric proteins. PR dimerization was detected by the ability of cotransfected GAL4/PR and VP16/PR chimeras in COS cells to induce expression of a reporter gene under the control of GAL4-binding sites (pG5CAT) (see Figure 3, page 1918). The claims are anticipated because the Leonhardt reference teaches a gene expression system comprising a first construct comprising DBD and a LBD from a nuclear hormone receptor, here, GAL4 and PR. The Leonhardt further teaches a second construct comprising a transactivation domain and an LBD from a nuclear hormone receptor not from USP, here the transactivation domain is VP-16 and the LBD is from PR, thus the claims are anticipated.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-5, 11 rejected under 35 U.S.C. 103(a) as being unpatentable over Leonhardt et al. (1998) in view of U.S. 59191667 (Gage et al.).

The instant claims are drawn to a gene expression modulation system wherein the first gene expression vector comprises a DBD and an LBD, and further wherein the LBD is from EcR; and a second gene expression vector which comprises a transactivation domain and an LBD either not from USP, or from RXR. The Leonhardt reference does not teach a gene expression system wherein the first construct comprises EcR and the second compromises RXR. However, the '667 patent discloses a transgenic animal contains one or more expression constructs containing nucleic acid encoding an ecdysone receptor, exogenous RXR, and an heterologous gene under the transcription control of an ecdysone response element. Therefore, it would have been obvious to one of skill in the art at the time the invention was made to make a gene expression modulation system wherein the first gene expression vector comprises a DBD and an LBD, wherein the LBD is an ecdysone receptor (EcR) LBD; and a second gene expression vector which comprises a transactivation domain and an LBD not from USP; and a reporter gene vector comprising a response element to the DBD of the first vector, wherein the gene expression system comprises an ecdysone receptor and an exogenous RXR. The motivation is provided in in transgenic mice containing an ecdysone response element and

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expressing ecdysone receptor and RXR, muristerone treatment can activate gene expression.

Thus, with tissue specific expression of ecdysone receptor and RXR and timely hormone treatment, inducible gene expression can be achieved with spatial, dosage, and temporal specificity.

### ***Conclusion***

Claims 2, 6, 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 7, 15 are objected to as being drawn to non-elected subject matter.

Claims 1, 3-5, 11 are rejected.

### ***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone

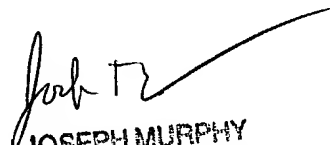
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are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
November 16, 2004



JOSEPH MURPHY  
PATENT EXAMINER